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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,337	03/10/2005	Shigeya Yamazaki	1422-0665PUSI	3502

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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11/29/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/527,337	Applicant(s) YAMAZAKI ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This application is a 371 of PCT/JP03/011806.

A preliminary amendment was filed dated Mar. 10, 2005. Claims 1-9 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes et al. US 4,721,723.

See whole article, especially examples 1-2 and claims 1-5. Please note that a product by process claim is a product. The same product of paroxetine hydrochloride containing 2.5% water for treating depression was disclosed by Barnes.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is unclear what is the molecular formula for the product as claimed “paroxetine hydrochloride hydrate”. Please note that ordinarily, a hydrate of a compound is referring to the compound and water in a 1:1 ratio. In the instant case, the water content of the products being described in the specification is about 2.4% (see examples 1-2) which is compatible to the 2.5-2.6% of the prior art (see Barnes ‘723, examples 1-2). Therefore, they are hemihydrates. No enabling description was found in the specification that a 1:1 ratio hydrate was produced.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Paroxetine hydrate/hemihydrate has been tested to be effective in treating depression (see Barnes '721, claim 6). Such efficacy in treating depression does not provide enabling support for the scope of claim 9 which encompassed enormous varieties of disorder with diverse etiology from pain, to obesity etc. for which no support can be found in the specification.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugi et al. in view of Ward et al. US 5,872,132 and Barnes US 4,723,723.

Determination of the scope and content of the prior art (MPEP §2141.01)

Sugi et al. (recited on 1449) disclosed process of making proxetine hydrochloride solvate using t-bu protected paroxetine in solvent with hydrochlorid acid (see p.529 right column).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process and product is that instead of paroxetine hydrochloride IPA solvate, the instant claims are for making hydrate. Ward et al. '132 taught that skilled person in the field knows about which solvent will form solvate/hydrate (col. 4, lines 10-20). Barnes et al. taught that in a solvent system that contains water, hydrate will result (see col.6-7, examples 1-2).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

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One having ordinary skill in the art in possession of the above references would be motivated to modify the Sugi process with the desirable solvent system containing water to produce the hydrate because the innate nature of the compound has been well recognized (Ward et al. '132) and the species of solvated variation using water has been known to form. One skilled in the art would be motivated to employ the one pot deprotection, salt forming and solvation of Sugi et al. using water with the expectation that a hydrated paroxetine hydrochloride will form. The product is well recognized, the one pot deprotection, salt formation and solvation process is readily available, thus, one would be motivated to use the teaching and suggestion of the prior art to obtain an expected hydrate product consistent with the result of the prior art.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes US 4,723,723 in view of Sugi et al. supplemented with Ward et al. '132.

Determination of the scope and content of the prior art (MPEP §2141.01)

Barnes et al. '723 disclosed process of making the claimed product (col. 6-7, examples 1-2) using the 2-chloroethyloxynol protecting group (see col. 6 line 30) in toluene/water.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is the using of t-butoxyl as the protecting group. Sugi et al. demonstrated, the t-butoxyl protected intermediate would be hydrolyzed into paroxetine solvate when appropriate solvent was used. Ward et al. '132 taught that the skilled person in the art would be well recognized the different solvent that will or will not form solvate (generic term including hydrate) with paroxetine (col. 4).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

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One having ordinary skill in the art would be well aware of all the pertinent art in the field. The above reference provided the innate property of paroxetine and the variation of solvent and N-protecting groups in the possession of artisan in the field. The instant claims are the mere picking and choosing among the various available N-protecting groups in combination with solvent systems with the results of the expected outcome of the particular choice of protecting group and solvent system. One skilled in the art would be motivated to modify the prior art processes with the combination because such teaching is well delineated in the references (Ward col. 4) and the suggestion has been clearly demonstrated by the success of the analogous process (Sugi et al.), and the expectation of obtaining the known compound is found in examples 1-2 using the toluene/water system.

6. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the allowed claims of copending Application No. 10/527.317.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant process are drawn generically using organic solvents in the presence of water which *fully* embraced the allowed scope wherein a specific organic solvent water ratio was specified i.e. a subgenus of the instant claims.

There is no good reason why applicants are entitled to continuous exclusivity of the same invention using the generic scope fully embracing the allowed claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

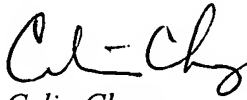
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 20, 2007


Celia Chang
Primary Examiner
Art Unit 1625